**Citation:**

Adachi Y, Sato C, Yamatsu K, Ito S, Adachi K, Yamagami T. A randomized controlled trial on the long-term effects of a 1-month behavioral weight control program assisted by computer tailored advice. *Behav Res Ther.* 2007 Mar; 45 (3): 459-470.

**PubMed ID:** 16713991

**Study Design:**

Randomized controlled trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine the long-term effects of a one-month behavior weight control program assisted by computer-tailored advice.

**Inclusion Criteria:**

- Female
- Ages 20 to 65 years
- BMI of 24kg/$m^2$ or more or BMI of 23kg/$m^2$ or more with mild hypertension, hyperlipidemia or diabetes mellitus.

**Exclusion Criteria:**

- BMI of 30kg/$m^2$ or more
- History of major medical or psychiatric problems or orthopedic problems that prohibited exercise
- If received a diet and exercise program within six months
- Currently, previously or planned to be pregnant within six months.

**Description of Study Protocol:**

**Recruitment**

Subjects were recruited through a local newspaper in Kyoto in January 2002.

**Design**

Randomized controlled trial in which subjects were randomly assigned to one of four treatment

groups:

- Full Kenkou-tatsujin program and an additional six months of self-monitoring of target behaviors and weight
- Full Kenkou-tatsujin program
- Kenkou-tatsujin booklet reading, seven months of self-monitoring of weight and walking steps measured by a pedometer
- Kenkou-tatsujin booklet reading only.

**Dietary Intake/Dietary Assessment Methodology**

Dietary habits were measured using questionnaires, including a 15-item brief lifestyle questionnaire.

**Intervention**

Subjects were randomly assigned to one of four treatment groups:

- Full Kenkou-tatsujin program and an additional six months of self-monitoring of target behaviors and weight
- Full Kenkou-tatsujin program
- Kenkou-tatsujin booklet reading, seven months of self-monitoring of weight and walking steps measured by a pedometer
- Kenkou-tatsujin booklet reading only.

The self-monitoring component of the intervention consisted of daily weight-monitoring and targeted behavior monitoring every day for a month.

**Statistical Analysis**

- Repeated measures analysis of variance was used to assess changes in weight, BMI, percent of weight loss and the Reduction Quotient
- Chi-square analysis was used to assess differences between groups in 5% or more weight loss and 7% or more weight loss groups of assigned condition
- Statistical significance was set at $P<0.05$ and Bonferroni adjustments were applied for multiple comparisons when significant with ANOVA.

**Data Collection Summary:**

- *Timing of measurements:* At baseline, one, three and seven months, body weights were measured in all participants and the questionnaire was completed. Height was measured at baseline. Also at baseline, one, three and seven months, a 15-item questionnaire was completed that assessed dietary and exercise habits
- *Dependent variables:* Height and weight were measured by study personnel, and BMI was calculated
- *Independent variables:* Basic subject characteristics, weight history and dietary and exercise habits were measured using a 15-item questionnaire.

**Description of Actual Data Sample:**

- *Initial N:* 205
- *Attrition (final N):* 198

- *Age:* 46.2±9.5 years
- *Anthropometrics:*
  - Mean BMI**:** 26.1±1.5kg/$m^2$
  - Mean weight: 64.6±6.2kg
- *Location:* Japan.

**Summary of Results:**

- All four groups had significant reductions in BMI and weight at seven months
- Those who followed the Kenkou-tatsunji program, with and without self-monitoring, had greater reductions in BMI and weight compared to the other groups at one month (P<0.05)
- The Kenkou-tatsunji with self-monitoring group also had great reductions in BMI and weight at months three and seven.

| | | Kenkou Program with Self-monitoring | Kenkou Program | Booklet with Self-monitoring | Booklet | F |
|---|---|---|---|---|---|---|
| **Body Weight** | 1M | -1.1±1.2 | -0.9±1.1 | -0.5±0.8 | -0.30±0.9 | 6.13** |
| | 3M | -2.3±2.0 | -1.7±1.9 | -1.3±1.5 | -1.1±1.5 | 3.94** |
| | 7M | -2.9±2.7 | -2.2±3.0 | -1.6±2.1 | -1.4±2.4 | 2.90* |
| **BMI** | 1M | -0.47±0.49 | -0.38±0.42 | -0.20±0.34 | -0.14±0.38 | 6.27** |
| | 3M | -0.93±0.85 | -0.69±0.73 | -0.53±0.64 | -0.44±0.60 | 3.96** |
| | 7M | -1.22±1.16 | -0.86±1.15 | -0.68±0.88 | -0.57±0.93 | 3.13* |

*P<0.05

**P<0.01

**Author Conclusion:**

The Kenkou program resulted in significant weight loss, especially when paired with a self-monitoring component.

***Reviewer Comments:***

*Details regarding the self-monitoring of a targeted behavior were minimal, and it is unclear whether the targeted behaviors included diet self-monitoring.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

**Relevance Questions**

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|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

**Validity Questions**

| | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | ??? |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |

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| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | No |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | No |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |

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| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | Yes |
| 6.6. | Were extra or unplanned treatments described? | Yes |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | No |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | No |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | Yes |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | No |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | No |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | No |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | No |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | No |
| 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | No |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |

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|---|---|---|
| 9.2. | Are biases and study limitations identified and discussed? | No |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |